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10/722,737	11/25/2003	Bradley S. Galer	BSG 021 US	7300

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,737	GALER, BRADLEY S.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are pending and under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 6/15/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hind (US 5411738) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia.

Hind discloses methods for treating nerve injury such as post-herpetic neuralgia with topical application of lidocaine to the skin at the site of the pain (Abstract and claims 1-8). As evidenced by MedlinePlus Medical Encyclopedia: Neuralgia, which is also known as postherpetic neuralgia, the symptoms include pain and **numbness** of the affected skin area (See symptoms pages 1-2 of 4). Numbness is a neuropathically-induced negative sensory phenomena (See [0011] pages 3-4 of the instant

specification). Therefore, the method of Hind inherently treats any neuropathically-induced negative sensory phenomena, such as numbness, because it is a symptom and associated with the disorder and instant claims 1-4 are anticipated. Hind discloses applying a patch which anticipates instant claim 5 (claims 2-6). Hind discloses from about 1-20% lidocaine which anticipates instants claim 6 and 7 (claim 5). Hind discloses a lidocaine patch with a non-woven polyester backing which anticipates instant claim 8 (column 15, lines 11-16 and claim 3). Hind discloses a method in column 15, lines 11-26:

> Study Drug and Placebo
> Lidocaine patches (Lidoderm Patch) contain an adhesive of 5% lidocaine base (700 mg/patch), water, glycerin, D-sorbitol, sodium polyacrylate, sodium carboxymethylcellulose, propylene glycol and other ingredients on a non-woven polyester backing. Vehicle placebo patches are identical except for the absence of lidocaine. The size of a single patch is 10×14 cm.
> Patch Application
> Prior to patch application, the painful area to be treated was marked and then photographed based on the subject's report of (1) the borders of the area of sensory abnormality, and (2) the area of greatest pain. Up to 3 patches were applied to cover the area of greatest pain as fully as possible within the limit of 420 cm^2 Of patch area.

Since 'backing' is being interpreted to mean a cover and any numbness is inherently treated by the method then instant claims 9-11 are anticipated.

Response to arguments:

Applicant asserts that the Medline is not prior art and that Medline cannot be used under 35 USC 102. Respectfully, the Examiner cannot agree. From MPEP

2131.01 III: Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

Applicant asserts that Medline is generally directed to neuralgia and Hind is directed to post-herpetic neuralgia and that there is nothing in Medline that indicates that numbness is a symptom of post-herpetic neuralgia. Respectfully, the Examiner cannot agree. The Medline reference, which by the way is a service of the *US National Library of Medicine and the National Institutes of Health* and therefore an authority of some credential, clearly states that postherpetic neuralgia is simply another name for neuralgia. There is nothing of record that says numbness does not accompany postherpetic neuralgia.

Applicant asserts that there is no inherent treatment of numbness when looking to Hind because Hind administers an effective dosage to treat pain and that there would be no need to treat pain if the patient was experiencing numbness because the pain would be masked by the numbness. While this argument is clever, it is not persuasive. The flaw in this line of reasoning is that the patient would be without pain all of the time. However, neuralgia is pain that follows the path of a specific nerve and the numbness is a symptom that goes along with that pain. The patient still has pain otherwise it wouldn't be neuralgia. Besides, the claim language is not limited to just numbness and Applicant defines broadly what is meant by neuropathic NSP in [0011]: "*Therefore, as used herein, the terms "NSP" or "neuropathic NSP" should be interpreted broadly to include all such neuropathic conditions and indications whether now known or later discovered. Such NSP are, by definition, functional disturbances considered to be caused by*

neuropathy…" Thus any functional disturbances caused by neuropathy, such as those caused in post-herpetic neuralgia would fall under this broad definition and would be treated by the method of Hind, as argued initially by the Examiner, in the absence of evidence to the contrary. The problem is that Applicant's 'neuropathically induced negative sensory phenomena' is simply fancy wordsmithery for describing symptoms because they are "by definition, functional disturbances considered to be caused by neuropathy…". The neuropathy is the underlying disorder and the method of Hind treats a neuropathy and inherently all the 'functional disturbances' that go along with it.

Respectfully, Applicant's arguments have been fully considered but are not persuasive. The Examiner maintains the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hind (US 5411738 (IDS filed on 4/30/04) in view of Wolicki (US 2004/0101582) as evidenced by MedlinePlus Medical Encyclopedia: Neuralgia.

Applicant claims a method for treating neuropathically-induced negative sensory phenomena comprising applying an anesthetic topically to the skin of a patient suffering from neuropathic negative sensory phenomena at or near the locus of the negative sensory phenomena.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The references of Hind and MedlinePlus are discussed in detail above and those discussions are hereby incorporated by reference.

Wolicki teaches in claim 6 the equivalence of various benzoic acid derivatives for the treatment of neuropathy:

> 6. The topical composition of claim 2, wherein said additional ingredient is selected from the group consisting of: capsaicin, lidocaine, bupivacaine, mepivacaine, ropivacaine, tetracaine, etidocaine, chloroprocaine, prilocaine, procaine, benzocaine, dibucaine, dyclonine hydrochloride, pramoxine hydrochloride, benzocaine, and proparacaine.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Hind is that Hind do not expressly teach various benzoic acid derivatives in the method. This deficiency in Hind is cured by the teachings of Wolicki.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add other benzoic acid derivatives, as suggested by Wolicki, to the method of Hind and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the art teaches the benzoic acid derivatives to be equivalent in methods of treating neuropathy. The expected result remains treatment of the neuropathy.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant essentially relies on the arguments against Hind and the Medline 102(b) rejection above and that Wolicki fails to cure those deficiencies. Respectfully, the Examiner cannot agree for the reasons provided *supra*. No unexpected results have been provided. The Examiner maintains the rejection.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/

Primary Examiner, Art Unit 1616